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MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF APRIL 18, 2006

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

MEETING OF THE PUBLIC HEALTH COUNCIL
OF THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
DOCKET: TUESDAY, APRIL 18, 2006, 10:00 A.M.
CHINA TRADE CENTER, DALEY CONFERENCE ROOM, 5TH FL.
2 BOYLSTON STREET, BOSTON, MA

1) **ROUTINE ITEMS: No Floor Discussion**

   a) Compliance with Massachusetts General Laws, Chapter 30A, §11A ½ - **No Vote**

   b) Records of the Public Health Council Meetings of December 20, 2005, January 24, 2006 and February 21, 2006 **(Approved)**

DETERMINATION OF NEED PROGRAM:

"INFORMATIONAL BRIEFING ON POSITRON EMISSION TOMOGRAPHY (PET)", By Joan Gorga, Acting Director, Determination of Need Program (No Vote/Infor. Only)

2) **COMPLIANCE MEMORANDUM:**

Previously Approved DoN Project No. 4-3A58 of Lahey Clinic Hospital, Inc. – Request for a significant change to increase the Project's Maximum Capital Expenditure and Gross Square Footage **(Approved)**

3) **CATEGORY 1 APPLICATIONS:**

   a) Project Application No.2-1468 of Quaboag on the Common to renovate a 141 Level II/III bed nursing facility and construct an on-site sewage treatment system **(Approved)**

   b) Project Application No. 4-4909 of Massachusetts General Physicians Organization, Inc. to provide Positron Emission Tomography services through acquisition of a PET/CT body scanner **(Approved)**

4) **CATEGORY 1 APPLICATIONS (COMPARABLE):**

   a) Project Application No. 4-3A93 of Brigham and Women's Hospital to expand Positron Emission Tomography services through acquisition of a PET/CT body scanner dedicated to evaluation of patients with cardiovascular disease **(Approved)**

   b) Project Application No. 4-4916 of Caritas PET Imaging to expand Positron Emission Tomography services through acquisition of a mobile PET/CT body scanner to serve 7 sites **(Approved)**

The Commissioner and the Public Health Council are defined by law as constituting the Department of Public Health. The Council has one regular meeting per month. These meetings are open to public attendance except when the Council meets in Executive Session. The Council's meetings are not hearings, nor do members of the public have a right to speak or address the Council. The docket will indicate whether or not floor discussions are anticipated. For purposes of fairness since the regular meeting is not a hearing and is not advertised as such, presentations from the floor may require delaying a decision until a subsequent meeting.

PUBLIC HEALTH COUNCIL

A regular meeting of the Public Health Council of the Massachusetts Department of Public Health was held on Tuesday, April 18, 2006, 10:00, at the China Trade Center, 2 Boylston Street, Daley Conference Room, Boston, Massachusetts. Public Health Council Members present were: Chair Paul J. Cote, Jr., Dr. Clifford Askinazi, Ms. Phyllis Cudmore, Mr. Matthew George, Jr., Ms. Maureen Pompeo, Mr. Albert Sherman, Ms. Janet Slemenda, Mr. Gaylord Thayer, Jr., and Dr. Martin Williams. Also in attendance was Attorney Susan Stein, First Deputy General Counsel, standing in for General Counsel Donna Levin who was absent.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control; Ms. Joan Gorga, Acting Director, Mr. Jere Page, Senior Program Analyst, and Bernard Plovnick, Consulting Program Analyst, Determination of Need Program.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETINGS OF DECEMBER 20, 2005, JANUARY 24, 2006, AND FEBRUARY 21, 2006:

Records of the Public Health Council Meetings of December 20, 2005, January 24, 2006 and February 21, 2006 were presented to the Council for approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the Records of the Public Health Council Meetings of December 20, 2005, January 24, 2006 and February 21, 2006 as presented.

"INFORMATIONAL BRIEFING ON POSITRON EMISSION TOMOGRAPHY (PET)", BY JOAN GORGA, ACTING DIRECTOR, DETERMINATION OF NEED PROGRAM:

Ms. Gorga made a slide presentation to the Council on Positron Emission Tomography (PET). Ms. Gorga spoke about PET: "What distinguishes it from other technologies and what makes it a valuable diagnostic service in health care today particularly in combination with CT scanning." It was noted that CT scanning is no longer considered a substantial change in service by the DoN program. Some excerpts from the presentation follow:

- CT locates masses in the body, but cannot determine if they are cancerous, while the PET can detect cancerous cells, but cannot exactly pinpoint their location. The current medical literature indicates that the fusion and correlation of these two imaging modalities has been shown to result in improved surgical planning, assessment of therapeutic response, and radiotherapy planning.

- PET scanning is a molecular imaging technique that detects chemical and metabolic changes in tissue at the cellular level – often before anatomic and structural changes (detected by conventional imaging such as X-ray) have had time to develop.

- PET allows the whole patient to be imaged at once permitting the identification of distant metastasis. This could be crucial in the development of treatment plans which could focus on either surgery or chemotherapy or a combination.

- Gamma radiation is produced from the positron-emitting fluorine and is detected by the PET scanner. The scanner records the signals that the tracer emits as it journeys through the body and is metabolized in targeted organs and the computer reassembles the signals into images.

- PET images and CT images are often fused to show metabolic function in an exact anatomic location. With a PET/CT scanner the images are fused automatically for a more accurate picture.

- The CT locates masses in the body but cannot determine if they are cancerous, while the PET can detect cancerous cells but cannot exactly pinpoint their location. The combination machine uses the capabilities of both diagnostic tools.

- PET is useful in diagnosing certain cancers, cardiovascular diseases and neurological diseases. PET imaging is also commonly used in the treatment of epilepsy and Alzheimer's disease.

- In cancer, PET is used to locate distant metastases which can alter treatment planning from surgical intervention to chemotherapy. It is used to determine the full extent of disease in tumor staging or grading. It is used to differentiate tumors as benign or malignant thereby avoiding surgical biopsy when the PET scan is negative. It is also used to differentiate tumor recurrence from other tissue growth which might occur as a result of radiation or surgery.

- In cardiology, PET is used to determine the viability of the tissue in the heart which is important in patients who may have suffered a previous heart attack and are now being considered as candidates for corrective heart surgery. PET can also be used in cardiac perfusion to measure the blood flow and pinpoint areas of decreased blood flow caused by blockages.

- In epilepsy treatment, PET is used to detect the areas of the brain causing epileptic seizures without the use of surgery and to determine if surgery is a treatment option.

- In Alzheimer's disease, PET is used to supply important diagnostic information and confirm an Alzheimer's diagnosis. It is used to illustrate areas where brain

activity differs from the norm.

- Lung cancer was one of the first uses of PET approved for reimbursement in the Medicare program and was approved in 1998...Use of PET scanning for lymphoma was approved for reimbursement by the Medicare program in 2001. The Medicare program approved PET scanning for breast cancer in 2002 and a Medicare recipient is eligible for reimbursement for a PET scan after change in treatment. Alzheimer's disease patients was included in Medicare reimbursement in 2004, however, coverage is limited to scans intended to differentiate between suspected Alzheimer's disease and other forms of dementias. PET scans for Parkinson's disease, renal cysts and Crohn's disease are not presently included in Medicare coverage but can be a valuable tool in diagnosis and treatment of these pathologies.

- Every year since 2000, new applications of PET have been approved for reimbursement by the Medicare program. The most recent approvals have made PET scans available to patients with other cancers such as ovarian, pancreatic and brain cancer.

No Vote/Information Only

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED DON PROJECT NO. 4-3A58 OF LAHEY CLINIC HOSPITAL, INC. – REQUEST FOR SIGNIFICANT CHANGE TO INCREASE THE PROJECTS MAXIMUM CAPITAL EXPENDITURE AND GROSS SQUARE FOOTAGE:

Ms. Joan Gorga, Acting Program Director, Determination of Need Program, presented previously approved Project No. 4-3A58 of Lahey Clinic Hospital to the Council, "The additional space is a result of detailed architectural plans which showed that the proposed renovations were inadequate. And since the DoN application only requests schematic line drawings, often the more detailed architectural plans required in the final plan review process, which are based on inspection behind the wall surfaces open by demolition show the adequacies of the original plans. The applicant requests significant changes that include increasing the maximum capital expenditure (MCE) from $55,346,000 (July 2003 dollars) to $87,288,915 (February 2006 dollars) and the gross square footage (GSF) from 110,471 to 200,105...The requested increase in MCE is the result of the construction. The total dollar increase in the MCE requested is 30% while the increase in renovation costs is 85% and the increase in new construction costs is 26%. The holder has indicated that many items in the budget, for example land development, planning and development and major movable equipment have not increased. Also, the holder has emphasized that the overall expansion of the project has occurred with a lower cost per GSF due to Lahey's efforts to contain costs and implement a variety of cost savings. While the increase requested for the gsf for the project is 81%, the increase in the MCE of 30% is significantly less. Staff notes that the requested costs per gsf for new construction and for renovation are less than the Marshall and Swift allowable cost/GSF for new construction of $428.59/GSF cited at the time of

the approval. Staff had determined whether the requested changes in gsf and MCE were reasonable in light of past decisions, were not foreseeable at the time the application was filed and were beyond the holder's control. Consistent with Council's past decisions, Staff finds that the increase in the GSF and MCE could not have been reasonably foreseen and were not reasonably within the control of the holder."

Attorney Andrew Levine, Donoghue, Barrett and McCue, Legal Counsel for the applicant; noted that the project should be completed in about a year. The applicant, Jeffrey Doran, aVice President of Lahey Clinic, accompanied him.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve the Request for a significant change on Previously Approved DoN Project No. 4-3A58 of Lahey Clinic Hospital, Inc., based on staff findings. This amendment approval provides for increase in MCE to $87,288,915 (February 2006 dollars) and increase in gsf to 200,105. This amendment is subject to the following conditions:

1. The approved GSF for this project shall be 200,105 including 159,591 gsf for new construction and 40,514 gsf for renovation.

2. The holder shall contribute 100.0% equity ($87,288,915 February 2006 dollars) toward the final approved MCE.

3. All other conditions attached to the original and amended approval of this project shall remain in effect.

CATEGORY 1 APPLICATIONS:

PROJECT APPLICATION NO. 2-1468 OF QUABOAG ON THE COMMON TO RENOVATE A 141 LEVEL II/III BED NURSING FACILITY AND CONSTRUCT AN ON-SITE SEWAGE TREATMENT SYSTEM:

Mr. Bernard Plovnick, Consulting Program Analyst, Determination of Need Program, presented the Quaboag project to the Council, "He noted that G/F Massachusetts, Inc. d/b/a Quaboag on the Common is a nonprofit skilled nursing facility located at 47 East Main Street, West Brookfield, MA. Originally built in 1850, the two-story building has been licensed as a nursing facility since 1968 and currently operates 98 Level II and 43 Level III beds. The proposed project, filed in January of 2004, seeks a Determination of Need for substantial renovation of the existing facility, notably the construction of an on-site sewage treatment system to bring Quaboag into compliance with Department of Environmental Protection ("DEP") regulations. In addition, the Applicant proposes to undertake minor interior renovations encompassing 59,925 gross square feet (GSF)."

Mr. Plovnick noted further: "During the DoN review process, Staff requested that the applicant provide a revised cost estimate for the waste water treatment plant. Based upon similar DoN approvals, staff recommends revised increases of $225,000 or 7%, and $54,000 or 6% to the proposed project capital expenditure and annual incremental

operating costs, respectively, to expedite the implementation of the project, which has been delayed by a lengthy regulatory process." The William H. Jankins Ten Taxpayer Group requested a public hearing, which was held on February 8, 2006 at West Brookfield Town Hall, 2 East Main Street, West Brookfield, MA. The TTG was not in attendance at the public hearing nor did it submit written comments on this application.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No.2-1468 of Quaboag on the Common**, based on staff findings, with a revised maximum capital expenditure of $3,271,501 (January 2004 dollars) and revised first year incremental operating costs of $761,929 (January 2004 dollars) . A staff summary is attached and made a part of this record as **Exhibit No. 14, 854.** As approved, the application provides for construction of an on-site sewage treatment system and renovations to the existing facility. This Determination is subject to the following conditions:

1. The Applicant shall accept the maximum capital expenditure of $3,271,501 (January 2004 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. The total approved gross square feet (GSF) for this project is 59,925 GSF of renovations to the existing facility.

3. The Applicant shall apply for a waiver from the Division of Health Care Quality for a unit size in excess of the 41-bed limit.

4. The Applicant shall maintain formal affiliation agreements with at least one local acute care hospital and one local home care corporation that address provision for respite services.

5. The Applicant shall, at the time of licensure, maintain Medicare certification for its eligible beds.

6. The Applicant shall establish a plan to protect the privacy, health and safety of the residents of the facility during the construction process.

7. Upon implementation of the project, any assets such as land, building improvements, or equipment that are either destroyed or no longer used for patient care, shall not be claimed for reimbursement for publicly aided patients.

8. The Department shall reserve the right to conduct a review of the financial feasibility of the project based on the Division of Health Care Finance and Policy's established rates of reimbursement for Medicaid patients at the time final maximum capital expenditures or any adjustments to the final maximum capital expenditure are submitted to the Determination of Need Program for approval in the event that such expenditures exceed the approved maximum capital expenditure. The Applicant shall submit a revised Factor Six (Financial

Schedules) upon request by the Department. The Applicant is advised that an increase in equity may be necessary to assure the financial feasibility of the project.

Staff's recommendation is based on the following findings:

1. G/F Massachusetts, Inc. d/b/a Quaboag on the Common seeks a Determination of Need for substantial capital expenditure to undertake interior renovations to the existing facility located at 47 East Main Street, West Brookfield, Massachusetts and to attain compliance with Department of Environmental Protection regulations with the construction of an on-site sewage treatment system.

2. The health planning process for this project was satisfactory.

3. Consistent with the May, 1993 DPH/DoN Guidelines for Nursing Facility Replacement and Renovation Guidelines, the Applicant has demonstrated need for substantial renovations to undertake site improvements, exterior building improvements, and interior renovations.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The revised and recommended maximum capital expenditure of $3,271,501 (January 2004 dollars) is reasonable, based upon similar, previously approved projects.

7. The revised and recommended incremental operating costs of $761,929 (January 2004 dollars) are reasonable based upon similar, previously approved projects.

8. The project is financially feasible and within the financial capability of the Applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project is exempt from the community health initiatives requirement.

11. A public hearing was held at the request of the William H. Jankins Ten Taxpayer Group which did not offer comments at the hearing or submit written comments.

PROJECT APPLICATION NO. 4-4909 OF MASSACHUSETTS GENERAL PHYSICIANS ORGANIZATION, INC.:

Mr. Jere Page, Senior Program Analyst, Determination of Need Program, presented Project No. 4-4909 of Massachusetts General Physicians Organization, Inc. to the Council. He said, in part, "...Staff finds need for the PET/CT unit proposed by MGPO and MGH at the Chelsea site. Staff notes the significant diagnostic benefits of PET and CT used in combination, and believes that a significant number of MGH's existing and future cardiac patients would benefit from the combination of these modalities. Staff finds that, based on data regarding the actual PET and PET/CT experience of MGH and Brigham and Women's Hospital, the estimated utilization for the existing and proposed MGH PET/CT units for patients in the Medicare approved clinical indications, exceeds the minimum volume of 1,250 scans for each unit required by the Guidelines. Staff notes that the proposed project will not have a negative impact on previously approved DoN PET or PET/CT scanners, since demand for each of the PET or PET/CT services, including the proposed MGPO/MGH unit, is institution specific with no reliance on outside referrals."

Mr. Page said further, 'We reviewed this as a fifth machine for MGH, as opposed to a standalone machine over in Chelsea. The recommended MCE is just under 3.2 million dollars to be funded through a 20% equity contribution, and the remaining 80% will be financed through tax exempt bonds issued by the Massachusetts Health and Educational Facility Authority. The protected interest rate right now is five percent for a five year term. The applicant has the usual conditions relative to community initiatives and interpreter services."

Discussion followed. Dr. Alan Fischman from MGH, Director of the PET Program, answered questions from the Council. He said that MGH has a backlog of patients waiting for the PET/CT scanner. "This additional camera will allow us to really expand our cardiac imaging unit", he said. Ms. Gorga noted that the guidelines allow for seven more units in the state and that there are also physician exempt machines serving patients throughout the state. Dr. Kevin Loughlin, representing Caritas PET Imaging, clarified for the Council that Blue Cross Blue Shield is the only insurance company in the state that will not cover the costs of scans for younger women with breast cancer.

Dr. Marcelo DiCarli of Brigham and Women's Hospital explained that the same machine is used for cancer and/or cardiac scans, "We use the same machine essentially, for both applications, and it is a seamless process of switching back and forth from cancer to cardiac scans. The only difference is, as we move into the future, we are going to see that PET/CT scanners that are primarily dedicated to cardiac applications will have perhaps a more advanced CT unit attached to the PET than the cancer units because of the use of CT for cardiac scanning and the potential ability of the combined study with the PET and CT to do a better job at diagnosing and also regarding management of a patient in fighting the disease. It is essentially the same machine."

Discussion continued. Council Member Maureen Pompeo asked staff to conduct a survey of the community hospitals to see what their PET service arrangements are presently. Council Member Sherman suggested that staff contact Peter Meade, Executive Vice-President of Blue Cross and Blue Shield, for the information. The various charges for scans had been discussed and the reasons for the different prices of the scans such as initial cost of machine, financing costs, volume of scans performed and the daily costs of doing business.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 4-4909 of Massachusetts General Physicians Organization, Inc.**, based on staff findings, with a maximum capital expenditure of $3,205,986 (February 2004 dollars) and first year incremental operating costs of $1,349,276 (February 2004 dollars). A staff summary is attached and made a part of this record as **Exhibit No.14,855**. As approved, the application provides for establishment of a Positron Emission Tomography (PET) service through acquisition of a combination PET/Computerized Axial Tomography (CT) scanner, and associated renovation to accommodate the new unit at the Mass. General Imaging Chelsea satellite clinic in Chelsea. This Determination is subject to the following conditions:

1. MGPO shall accept the maximum capital expenditure of $3,205,986 (February 2004 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. MGPO shall contribute 20% in equity ($641,197 in February 2004 dollars) toward the final approved MCE.

3. MGPO shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.

4. MGPO has agreed to provide a total of $ 160,000 (February 2004 dollars) over five years to fund the following community health services initiatives:

    a) $20,000 per year over five years for a total of $100,000 will be provided to expand the Child Protection Consultation Team to Chelsea by providing a part-time social worker in the City of Chelsea to consult with providers on cases involving child abuse and neglect. The Child Protection Consultation Team will provide a full range of appropriate support and services to children and their families including screening, identifying, assessment, intervention, referral, and follow-up services on suspected cases of child abuse and neglect.

    b) $12,000 per year over five years for a total of $60,000 will be provided to support an annual community forum or its equivalent conducted by/with the Harbor Area Alliance (Community Health Network Area (CHNA) #19) to assess emerging community health needs in the Chelsea area, and

to inform funding priorities for the CHNA's existing mini-grant program as well as fund additional programs based on health priorities that may emerge from the annual forum. Details of this process will be determined collaboratively by MGPO representatives, the Greater Boston Regional Office of Healthy Communities, OHC and the CHNA.

Funding will begin upon project implementation and notification to the OHC and CHNA #19 at least two weeks prior to implementation of the PET/CT services at Mass. General Imaging Chelsea, and both MGPO and the CHNA will submit written annual reports to the OHC regarding progress of these initiatives.

Staff finds that, with adherence to a certain condition, the project meets the community health initiatives of the DoN Regulations.

5. With regards to its interpreter service, MGPO shall:

   - Develop a reliable and valid system for the collection of self-reported race and ethnicity information from patients.

   - Develop a formal plan and provide the necessary systemic support to expand outreach to more non-English speaking communities throughout HSA IV.

   - Translate patient education documents and signage into the most commonly spoken languages in the service area as needed.

   - Submit the Annual Language Needs Assessment on the anniversary of the DoN date, utilizing internal and external data. Involve community-based organizations in the Annual Needs Assessment.

   A plan to address these interpreter service elements shall be submitted to the Office of Multicultural Health (OMH) within 120 days of the DoN approval, and MGPO shall notify OMH of any substantial changes to its Interpreter Services Program. Also, MGPO shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care.

Staff's recommendation was based on the following findings:

1. MGPO proposes to establish a Positron Emission Tomography (PET) service through acquisition of a combination PET/Computerized Axial Tomography (CT) scanner and associated renovation to accommodate the new unit at the Mass. General Imaging in Chelsea.

2. The project meets the requirements of the health planning process consistent with Guidelines for Positron Emission Tomography (Guidelines).

3. MGPO has demonstrated demand for the proposed PET/CT service, as discussed under the Health Care Requirements factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $3,205,986 (February 2004 dollars) is reasonable, based on a similar, previously approved project.

7. The recommended incremental operating costs of $1,349,276 (February 2004 dollars) are reasonable for a PET/CT unit and related renovation to accommodate the unit.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.

CATEGORY 1 APPLICATIONS (COMPARABLE):

PROJECT APPLICATION NO. 4-3A93 OF BRIGHAM AND WOMEN'S HOSPITAL:

Mr. Jere Page, Senior Program Analyst, Determination of Need Program, presented the Brigham and Women's Hospital (BWH) to the Council. He noted, "...The Brigham and Women's proposes to extend its Positron Emission Tomography at the hospital. That is going to require a combination of PET/CT scanner and this scanner will be dedicated to evaluation of patients with cardiovascular disease. This project was reviewed against the DoN review factors of the Guidelines for PET services and staff has determined that the PET service will exceed minimum volume requirements as well as provide more accessible cardiac services, PET/CT services to the patients in the Brigham's primary service area. The recommended MCE is just over four million dollars and will be provided through a 100% equity contribution by the BWH from their available unrestricted planned replacement expansion funds." Staff further noted that the project has the usual conditions regarding community initiatives ($210,000 dollars over five years) and interpreter services.

Discussion Followed: It was noted that the Mass General Hospital application was not comparable to the other two PET applications because it was filed in a different filing period and had no Ten Taxpayer Group. It was further noted that Community Health Initiatives are based on five percent of the projected maximum capital

expenditure. Council Member Askinazi asked why BWH and MGH had separate PET programs – why not one central location, under one director to reduce costs and share expertise, i.e., the reading of scans would probably improve because of increased volume. Ms. Gorga, Acting Director, Determination of Need Program, replied, "I think your question is well taken for some other projects, but I am not sure it is well taken for these because the volume on these will be large enough to justify its own unit. Some of the units we have seen will be doing 1600 and that is different than these that will be doing up to seven thousand. I think you are going to get the economies of scale, and you are going to get the benefit of seeing the radiologists reading many PET scans at both of these projects because the volumes are going to be very high. But your point may be well taken with a smaller community hospital or community hospital plus teaching hospital, which is one of the reasons we have been encouraging the hospitals to join together, to make multi-hospital consortiums, and indeed the last batch that we saw did have Mount Auburn and Winchester coming together. It did have South Coast, which was serving as the PET scanner for three of its hospitals...We are encouraging that kind of collaboration, but with these hospitals, I think the volumes are going to be large enough to justify their own units."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 4-3A93 of Brigham and Women's Hospital**, based on staff findings, with a maximum capital expenditure of $4,050,000 (February 2005 dollars) and first year incremental operating costs of $1,060,496 (February 2005 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14, 856**. As approved, the application provides for expansion of a Positron Emission Tomography (PET) service through acquisition of a combination PET/Computerized Axial Tomography (CT) scanner dedicated to the evaluation of patients with cardiovascular disease. This Determination is subject to the following conditions:

1. Brigham and Women's shall accept the maximum capital expenditure of $4,050,000 (February 2005 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Brigham and Women's shall contribute 100% in equity (February 2005 dollars) toward the final approved MCE.

3. Brigham and Women's shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.

4. Brigham and Women's shall provide a total of $210,000 (February 2005 dollars) over five years to fund the following community health service initiatives:

    a) $15,000 per year over five years for a total of $75,000 will be provided to support community mini-grants issued through the Alliance for Community Health (Boston Community Health Network Area ("CHNA #19")) that fund community prevention programs to be determined by

CHNA #19.

b) $4,000 per year over five years for a total of $20,000 will be provided to CHNA #19 to provide support for the CHNA's administrative expenses.

c) $11,500 per year over five years for a total of $57,500 will be provided to support expansion and evaluation of Boston-area programs addressing teen violence prevention.

d) $11,500 per year over five years for a total of $57,500 will be provided to support expansion and evaluation of Boston-area programs to address obesity and weight reduction.

Funding will begin upon project implementation and notification to both the Office of Healthy Communities ("OHC") and CHNA#19 at least two weeks prior to implementation of the proposed cardiac PET/CT units, and CHNA #19 will submit written annual reports to Brigham & Women's and the OHC regarding progress of these initiatives.

5. With regards to its interpreter service, Brigham and Women's shall:

- Develop procedures detailing when to use volunteer staff interpreters, how to access them and how their responsibilities will be met when working as volunteer trained interpreters;

- Develop a detailed plan for training clinical, support and administrative staff on the appropriate use of interpreters inclusive of monitoring the use of the online training video on the appropriate use of interpreters;

- Establish a plan to ensure the availability of and assuring the quality of interpreter services at its affiliated practices and centers;

- Establish a formal plan identifying the systemic support to conduct outreach to non-English speaking communities throughout HSA IV;

- Monitor the practice of use of overhead pages and reluctance to use face to face interpreters

In addition, Brigham and Women's shall submit a language needs assessment and a plan to address the above requirements to The Office of Multicultural Health (OMH) within 120 days of the DoN approval, and the Hospital shall notify OMH of any substantial changes to its Interpreter Services Program. Also, the Hospital shall follow recommended National Standards for Culturally and Linguistically Appropriate Services ("CLAS") in Health Care. Brigham & Women's will also provide an annual progress report to OMH on the anniversary date of the DoN approval.

PROJECT APPLICATION NO. 4-4916 OF CARITAS PET IMAGING: TO EXPAND POSITRON EMISSION TOMOGRAPHY SERVICES THROUGH ACQUISITION OF A MOBILE PET/CT BODY SCANNER:

Mr. Jere Page, Senior Program Analyst, Determination of Need Program, presented Project Application No. 4-4916 to the Council. He said, "Caritas PET Imaging is proposing to expand its PET Service through a mobile PET/CT scanner. It will serve the following clinic satellite locations; Caritas St. Elizabeth's Medical Center, Boston; Caritas Good Samaritan Medical Center, Brockton; St. Anne's Hospital, Fall River; Caritas Norwood Hospital (Satellite in Foxboro); Tufts New England Medical Center, Boston; Caritas Carney Hospital, Boston; and Milton Hospital, Milton. This project was reviewed against the DoN application review factors and guidelines. Based on this review, we have determined that it will exceed the minimum volume requirements and provide more accessible PET services to these seven service areas. The recommended MCE is just over two million dollars and represents the fair market value of the mobile PET/CT unit, which will be provided under a lease arrangement with GE Medical Systems."

In regard to the community initiatives condition, Mr. Page also noted that the applicant will provide $20,000 per year, for a total of $100,000 over five years, to fund or assist in four different CHNAs: #s 19, 20, 22 and 25. CHNA #19 is in Boston and the other CHNAs are in the service areas of the satellite locations. Discussion followed, Council Member Cudmore asked if this mobile unit was a cost effective model. Attorney Andrew Levine on behalf of the applicant said, "...What we are finding is as of right now it is cost effective in terms of meeting the needs of the patient. Although it is a costly model, it is working...as each hospital's volume grows, eventually, it may transition to fixed units over time, but we are really years away. It is our way of having a model that gets a licensed clinic to each site in a scheduled way, so that the physicians there can plan to have each site served and it is working fairly well. As you can tell, we are trying to, as Council has asked, get into the communities...We are making sure that those patients in the community are able to get access to PET in what we consider a cost effective way."

Dr. Kevin Loughlin of Caritas PET Imaging added, "I agree, otherwise, these folks would not have any access to PET scanning, as they didn't before we were in existence. People were disadvantaged. They would have to go into Mass. General Hospital... and there was a two or three week wait early on for folks to come and get a PET scan. How many people would like to have a diagnosis of breast cancer and be told, well, you really need a PET scan, but you can't get one for three weeks. We have been able to take this technology to these communities that otherwise didn't have it and bring expertise to the local medical community, to learn how to interpret these examinations and, if at some point their volume is

such and their patient population is such, they might be able to get their own fixed scanners."

Council Member Dr. Martin Williams noted for the record that he recused himself from voting since he is employed by Caritas Carney Hospital. Council Member Sherman moved to approve staff's recommendation of approval.

After consideration, upon motion made and duly seconded, it was voted unanimously (except Dr. Williams who recused himself) to approve **Project Application No. 4-4916 of Caritas PET Imaging, LLC,** based on staff findings, with a maximum capital expenditure of $2,019,000 (February 2005 dollars) and first year incremental operating costs of $1,625,409 (February 2005 dollars). A Staff Summary is attached and made a part of this record as **Exhibit No. 14, 857**. As approved, the application provides for expansion of existing mobile Positron Emission Tomography (PET) service through acquisition of a mobile combination PET/Computerized Axial Tomography (CT) scanner, which will serve the following clinic satellite locations: Caritas St. Elizabeth's Medical Center, Boston; Caritas Good Samaritan Medical Center, Brockton; St. Anne's Hospital, Fall River; Caritas Norwood Hospital (licensed satellite in Foxboro); Tufts-New England Medical Center, Boston; Caritas Carney Hospital, Boston; and Milton Hospital, Milton. This Determination is subject to the following conditions:

1. Caritas shall accept the maximum capital expenditure of $2,019,000 (February 2005 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Caritas shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.

3. Caritas has agreed to provide $20,000 (February 2005 dollars) per year for five years for a total of $100,000 to assist Community Health Network Areas ("CHNA's" 19, 20, 22, and 25) in addressing select related needs of residents in the primary service areas of the seven Caritas satellite clinic locations. Each CHNA, in consultation with the Office of Healthy Communities ("OHC"), will design programs to assist its communities in addressing select cancer detection, prevention and related needs, especially in the low income and elderly population. This program funding can include training mini-grants or program support, and Caritas is encouraged to send a representative to participate in each CHNA's planning for this funding. These programs will build upon established activities within the various CHNA communities that enhance the health of the community through community-based prevention planning and health promotion. Each CHNA will incorporate the use of established models in its program planning, and each will submit written annual reports to Caritas and the OHC regarding its program outcomes and budget. Funding will begin upon project implementation and notification to

the OHC at least two weeks prior to implementation.

4. With regards to the interpreter services at each clinic satellite site, Caritas shall:

    - Collect "client preferred language for discussing health related concerns" at the time of each client's referral for PET/CT services.

    - Ensure each Limited English Proficiency (LEP) client access to competent interpreter services through telephonic assessment/discussion prior to the date of the PET/CT procedure.

    - Ensure each LEP client receives competent interpreter services as needed at the time of the PET/CT procedure.

    - Develop a mechanism for tracking interpretation sessions by language and hospital and provide annual statistics regarding these sessions to the Office of Multicultural Health.

Staff's recommendation is based on the following findings:

1. Caritas proposes to expand its existing mobile Positron Emission Tomography (PET) service through acquisition of a mobile combination PET/Computerized Axial Tomography (CT) scanner, which will serve the following clinic satellite locations: Caritas St. Elizabeth's Medical Center, Boston; Caritas Good Samaritan Medical Center, Brockton; St. Anne's Hospital, Fall River; Caritas Norwood Hospital (licensed satellite in Foxboro); Tufts-New England Medical Center, Boston; Caritas Carney Hospital, Boston; and Milton Hospital, Milton.

2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).

3. Caritas has demonstrated demand for the proposed PET/CT service, as discussed under the Health Care Requirements factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $2,019,000 (February 2005 dollars) is reasonable, based on a similar, previously

approved project.

7. The recommended incremental operating costs of $1,625,409 (February 2005 dollars) are reasonable for a PET/CT unit and related hospital construction to accommodate the unit.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.

11. The Mark R. Taylor Ten Taxpayer Group (TTG) registered in connection with the proposed project, but did not submit written comments or request a public hearing.

12. This project is one of two comparable applications filed by Caritas PET Imaging, LLC (Project No. 4-4916), and Brigham and Women's Hospital (Project No. 4-3A93). When considered alone, both applications are capable of being approved, since each has demonstrated demand for PET/CT services. A detailed comparability analysis was not undertaken since these two applications each meet all the review factors of the PET Guidelines.

This meeting adjourned at 11:00 a.m.

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Paul J. Cote, Jr.
Chair

LMH/lmh